ORBUS
MEDICAL TECHNOLOGIES INC.

JUL 31 2001

510(k) Summary

1. **Submitter:** Orbus Medical Technologies, Inc
5363 NW 35th Ave
Fort Lauderdale, Florida 33309
Phone: (954) 730-0711
Fax: (954) 730-7601

2. **Contact:** Robert F. Frechette
Director of Regulatory Affairs

3. **Date Prepared:** January 5, 2001

4. **Device Trade Name:** R Stent Biliary Endoprosthesis

5. **Device Common Name:** Biliary stent

6. **Device Classification:** Biliary Catheter (78 FGE)

7. **Predicate Devices:** Intra Therapeutics Instrastent Biliary Endoprosthesis
Cordis Palmaz Balloon Expandable Stent
Guidant MegaLink Biliary Stent
Cordis Corinthian Transhepatic Biliary Stent

8. **Description:**

The R Stent Biliary Endoprosthesis is a permanently implanted device used to maintain patency of a major bile duct obstructed by tissue of an impinging tumor. The device is a balloon expandable stent made by laser cutting an open lattice design into a 316L stainless steel tube. The stent is designed to be manually crimped onto a PTA balloon catheter, inserted percutaneously to the diseased site, and deployed by balloon inflation. The stent is available in diameters ranging from 6mm to 10mm and corresponding lengths of 15, 18, 26, 36, 56, 76, and 94mm. The lattice pattern contains a triple helix configuration with strut widths of 0.007"-0.008" and thickness of 0.009".

9. **Intended Use:**

The R Stent Biliary Endoprosthesis is intended for the palliation of Malignant neoplasms in the biliary tree.

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10. Technological Characteristics:

Comparisons of the new and predicate devices show that the technical characteristics such as materials, performance properties, biocompatibility, method of sterilization, and packaging are identical or substantially equivalent.

11. Performance Data:

Orbus completed in vitro tests such as deployment, expansion force testing, compression force testing, dimensions, and corrosion testing. The results indicated that the R Stent Biliary Endoprosthesis performed in a manner substantially equivalent to the predicate devices.

12. Conclusion

Since the R Stent Biliary Endoprosthesis has the same intended use, identical material properties, similar performance properties, packaging, and sterilization methods, it may be considered substantially equivalent to the predicate devices cited in (7).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2001

Mr. Peter Piferi
Vice President of Operations
Orbus Medical Technologies, Inc.
Corporate Headquarters
5363 NW 35th Avenue
Fort Lauderdale, Florida 33309

Re: K010107
R Stent Biliary Endoprosthesis
Dated: April 27, 2001
Received: May 2, 2001
Regulatory Class: II
21 CFR §876.5010/Procode: 78 FGE

Dear Mr. Piferi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010107

Device Name: R Stent Biliary Endoprosthesis

FDA's Statement of the Indications For Use for device:

The R Stent is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010107